

## REMARKS

This request for continued examination is filed in response to the Final Rejection of September 24, 2008. Claims 1 and 15 are currently amended to further define the claim terms “a compound” and “a microbially-based infection.” With respect to the former, the compounds set forth in dependent claims 5, 12, 19, and 26 have been amended into claims 1 and 15. Accordingly, claims 5, 12, 19, and 26 are cancelled without prejudice to Applicants right to pursue these claims individually in a divisional, continuation, or continuation-in-part. Claims 1 and 15 have also been amended to recite that the “microbially-based infection” may be comprised of either a *mycobacteria* or *rhodococci*. Support for each of the foregoing amendments may be found in at least the originally filed claims, as well as pages 4-11 and 22-30 of the originally filed specification. To this end, no new matter is being introduced. Finally, claim 28 has been amended to depend from claim 15, and claims 6- 11, 13, 20-25, and 27, which were previously withdrawn from consideration in the response of June 27, 2008, are hereby indicated as being cancelled.

The present application relates to methods of treating a subject with a microbially-based infection by administering one or more compounds that reduce energy levels within the bacterial cells. These compounds specifically induce overexpression of the b-subunit of the enzyme ATP synthase, which results in an overall reduction of ATP levels by at least 10%. Such compounds exemplified within the present application include those of formulas I-VIII, as set forth in the originally filed claims as well as page 3 of the originally filed specification. Microbially-based infections are exemplified as those of the genera *mycobacteria* and *rhodococci*, as set forth on pages 4-11 and 22-30 of the originally filed specification. Although Applicants steadfastly assert that the present application is not limited to these compounds and microbes, in the interest

of furthering prosecution, the claims provided herein have been amended accordingly.

Applicants assert, in view of the arguments below, that these amendments overcome the instant rejections and place these claims in a condition for allowance.

I. Rejections under 35 U.S.C. 112, first paragraph

A. Rejections maintained

The terms “compound” and “microbially-based infections,” as recited in claims 1-5, 12, 14-19, and 26, were rejected for failing to comply with the written description requirement. Both terms were argued to be inadequately described within the specification to reasonably convey possession of the invention. The compounds recited in claims 5 and 19, however, were suggested to be sufficiently described. Likewise, the microbially-based infections of claims 14 and 28 were also suggested to be sufficiently described. Nevertheless, because none of claims 1-5, 12, 14-19, and 26 provided both of these exemplifications within one claim (as was recited in claim 28), the foregoing rejection was maintained.

Independent claims 5 and 19 have been cancelled without prejudice and the claim recitations incorporated into independent claims 1 and 15. Accordingly, Applicants have defined the term “compound” to be any one of Formulas I-VIII. As suggested in the instant office action, Applicants assert that this amendment traverses the rejection of these claims, at least with respect to the term “compound.”

Independent claims 1 and 15 have also been amended to recite that the term “microbially-based infections” are either *mycobacteria* or *rhodococci* infections. While this amendment presents a slight departure from the subject matter suggested to overcome the rejection, Applicants respectfully assert that adequate support for such amendment is pervasive throughout

the instant specification. Pages 4-10 and 22-30 of the originally filed specification, for example, provide the targeted mechanism characteristic of the *mycobacteria* genus. Page 11, in particular, provides additional support for exemplified species of *mycobacteria*, as well as the *rhodococci* genus. Applicants respectfully assert that these pages provide that the inventors were in possession of the invention at the time of filing and that the foregoing amendment traverses the rejection of these claims.

#### B. New Matter Rejection

Claims 1-5, 12, 14-19, 26 and 28 were also rejected for new matter. Specifically, the claim amendment changing Y from –NH to –NH<sub>2</sub> was identified as not being supported by the application, particularly PCT/US98/17830. As indicated above, this element was removed from the foregoing claims. Accordingly, Applicants respectfully assert that the rejection is moot.

#### II. Rejection of the claims under 102(e)

In the instant office action claims 1-5, 12, 14-19, 26 and 28 were rejected under 35 U.S.C. 102(e) as anticipated by U.S. 2006/0247302 to Kuhajda, et al. (hereinafter “Kuhajda”). Kahajda was argued to teach compound VII and the required step of administering an effective amount of the compound to a subject in need of treating a microbially-based infection. The decrease in ATP levels, requirement that the compound cause overexpression of the b-subunit of ATP synthase, and dosaging so as not to kill mammalian cells were deemed inherent properties of the compound. Accordingly, the rejection of these claims was maintained.

Applicants respectfully assert that Kuhajda does not teach administration of the compounds as currently amended. Kuhajda relates to a family of FAS inhibitory compounds, of which compound VII is inclusive, useful for any one of a number of functions, including cancer

therapy, obesity, and as anti-microbials. With respect to anti-microbial activity, however, Kuhajda admits that FAS inhibitors are not universally applicable. Indeed, paragraphs 0016 through 0023 outline distinguishing features of FAS enzymes within various bacteria genera and imply that many known FAS inhibitors do not always work for every organism targeted. (See paragraph 0016, for example) With this in mind, Kahajda sets forth that the microbial infections envisioned for treatment by the compounds disclosed are limited to *staphylococci* and *enterococci* infections. (see paragraph 0081) These organisms, along with *Pseudomonas aeruginosa* and *Escherichia coli*, were the only organisms tested by Kuhajda (see paragraphs 0178 – 0180) and the only organisms shown to be affected.

As noted above, the claims of the present invention have been amended to recite that the microbially-based infection is either a *mycobacteria* or *rhodococcus*. The applicability of the recited compounds to these organisms was specifically tested, with supporting data being outlined in the Examples of the instant application. Kuhajada, while providing a broad genus of applicability for compound VII, does not provide specific teachings related to either of these genera. At best, Kuhajda presents data for the usefulness of its compounds on the handful of organisms studied with an invitation to investigate their applicability on other organisms.

The MPEP 2112 (section IV) expressly states that, “‘an invitation to investigate is not an inherent disclosure’ where a prior art reference ‘discloses no more than a broad genus of potential applications of its discoveries.’” Kuhajda certainly relays the usefulness of its compounds in several broad genera, but only provides support for *staphylococci*, *enterococci*, *Pseudomonas aeruginosa* and *Escherichia coli*. Kuhajda stops short of showing applicability outside of these species, and implicitly opens the door for future investigation. Whether these compounds will work within organisms outside of those tested, is acknowledged by Kuhajda to

be conjecture. Under MPEP 2112, this is insufficient to uphold a rejection of the present claims as inherent.

Accordingly, Applicants respectfully submit that the present claims, as amended, traverse the foregoing rejection.

## CONCLUSION

Applicants respectfully submit that this Response addresses the issues of the Final Office Action of September 24, 2008 in full, and the presently amended claims are in condition for allowance. If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that the Examiner telephone Applicants' attorney at (215) 299-2772 to discuss any additional rejections.

The USPTO is authorized to charge Deposit Account No. 50-1943 for any charges in connection with this matter.

Respectfully Submitted,

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